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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,864	11/30/2006	Takashi Shinohara	701067	1275
23460	7590	01/22/2008	EXAMINER	
LEYDIG VOIT & MAYER, LTD			SGAGIAS, MAGDALENE K	
TWO PRUDENTIAL PLAZA, SUITE 4900			ART UNIT	PAPER NUMBER
180 NORTH STETSON AVENUE				1632
CHICAGO, IL 60601-6731				
			MAIL DATE	DELIVERY MODE
			01/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/594,864	SHINOHARA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Magdalene K. Sgagias	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 19 September 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-34 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

Claims 1-34 are pending.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, drawn to a method of producing pluripotent stem cells, which comprises culturing testis cells using a medium containing glial cell derived neurotrophic factor (GDNF) or an equivalent thereto to obtain pluripotent stem cells.

Group II, claim(s) 17-19, drawn to a pluripotent stem cell derived from a testis cell, which is positive for at least any one selected from the group consisting of SSEA-1, Forsman antigen, 131- integrin,  $\alpha$ 6-integrin, EpCAM, CD9, EE2 and c-kit.

Group III, claim(s) 20, drawn to a method of producing a chimeric embryo, which comprises the following steps: (Step 1) culturing testis cells using a medium containing glial cell derived neurotrophic factor (GDNF) or an equivalent thereto to obtain pluripotent stem cells.

Group IV, claim(s) 21, drawn to A method of producing a chimeric animal (excluding humans), which comprises the following steps (Step 1) culturing testis cells using a medium containing glial cell derived neurotrophic factor (GDNF) or an equivalent thereto to obtain pluripotent stem cells; (Step 2) introducing the pluripotent stem cells into a host embryo to obtain a chimeric embryo; (Step 3) transferring the chimeric embryo to the uterus or oviduct of a host animal to obtain a chimeric animal (excluding humans)

Group V, claim(s) 22, drawn to A method of producing a non-human animal derived from pluripotent stem cells, which comprises the following steps: (Step 1) culturing testis cells using a medium containing glial cell derived neurotrophic factor (GDNF) or an equivalent thereto to obtain pluripotent stem cells; (Step 2) introducing the pluripotent stem cells into a host embryo to obtain a chimeric embryo; (Step 3) transferring the chimeric embryo to the uterus of a host animal to obtain a chimeric animal (excluding humans); (Step 4) mating the chimeric animal to obtain a non-human animal derived from the pluripotent stem cells.

Group VI, claim(s) 23, drawn to a method of producing a tetraploid chimeric embryo, which comprises the following steps: (Step 1) culturing testis cells using a medium containing glial cell

derived neurotrophic factor (GDNF) or an equivalent thereto to obtain pluripotent stem cells; (Step 2) introducing the pluripotent stem cells into a tetraploid embryo to obtain a tetraploid chimeric embryo.

Group VII, claim(s) 24, drawn to 24 a method of producing a non-human animal derived from pluripotent stem cells, which comprises the following steps: (Step 1) culturing testis cells using a medium containing glial cell derived neurotrophic factor (GDNF) or an equivalent thereto to obtain pluripotent stem cells; (Step 2) introducing the pluripotent stem cell into a tetraploid embryo to obtain a tetraploid chimeric embryo; (Step 3) transferring the tetraploid chimeric embryo to the uterus or oviduct of a host animal to obtain a non-human animal derived from the pluripotent stem cells..

Group VIII, claim(s) 25-31, drawn to a method of producing functional cells, which comprises the following steps: (Step 1) culturing testis cells using a medium containing glial cell derived neurotrophic factor (GDNF) or an equivalent thereto to obtain pluripotent stem cells; (Step 2) culturing the pluripotent stem cells under functional cell differentiation conditions to obtain functional cells.

Group IX, claim(s) 32-34, drawn to a composition for producing pluripotent stem cells derived from a testis cell, which contains glial cell derived neurotrophic factor (GDNF) or an equivalent thereto.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the inventions of Groups I-IX is culturing testis cells using a medium containing glial cell derived neurotrophic factor (GDNF) or an equivalent thereto to obtain pluripotent stem cells. **Nagano et al**, (Biology of Reproduction, 68: 2207-2214, 2003) teaches a method for producing stem cells by culturing mouse cryptorchid testis using a medium containing GDNG (p 2208, and figure 3). Therefore the instant technical feature of Groups I-IX does not make a contribution over the prior art. Furthermore, the claimed methods of Groups I, III-VIII have distinct method steps, produce different products and/or results, which are not coextensive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgalias whose telephone number is (571) 272-3305. The

Application/Control Number:  
10/594,864  
Art Unit: 1632

Page 4

examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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Art Unit 1632

/Anne-Marie Falk/  
Anne-Marie Falk, Ph.D.  
Primary Examiner, Art Unit 1632